EXHIBIT B

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United States District Court,
C.D. California.
The MANNKIND SECURITIES ACTIONS.

No. CV 11–00929 GAF (SSx).
Dec. 16, 2011.

Darcie Allison Tilly, Koji F. Fukumura, Meghan O'Ryan Spieker, Peter M. Adams, Cooley Godward Kronish, San Diego, CA, for The Mannkind Securities Actions.

ORDER RE: MOTIONS TO DISMISS AND TO STRIKE

GARY ALLEN FEESS, Judge.

***1** Renee Fisher, Deputy Clerk.

I. INTRODUCTION

Shareholders of MannKind Corporation, developer of an inhalable insulin treatment for diabetes, bring this securities fraud class action against the company and a number of its senior officers, alleging that Defendants serially misrepresented to investors facts relating to the existence and likelihood of FDA approval. Defendants now move to dismiss Plaintiffs' complaint on the ground that it fails to meet the heightened pleading requirements for claims of securities fraud, and to strike an expert report attached to the complaint. For the reasons set forth below, the Court finds that the complaint is adequately pleaded, and that the expert report is properly attached thereto. Accordingly, the Court **DENIES** both motions.

II. BACKGROUND

This securities class action is brought on behalf of all persons who purchased or otherwise acquired the common stock of MannKind Corporation ("MannKind") between May 4, 2010 and February 11, 2011 (the "Class Period"), against MannKind and certain of its officers and/or directors (collectively, "Defendants"). (Docket No. 56, Corrected Consolidated Class Action Compl. ("CC") ¶ 1.) The complaint alleges that Defendants violated §§ 10(b) and 20(a) of the Securities Exchange Act of 1934 by making "various untrue statements of material facts and [by] omitt[ing] to state material facts necessary in order to make the statements made," with the intent to deceive the investing public, artificially inflate and maintain the market price of MannKind securities, and cause Plaintiffs to purchase MannKind common stock and options at artificially inflated prices. (*Id.* ¶ 121)

In deciding a motion to dismiss, the Court must accept all well-pleaded factual allegations in the complaint as true. *Blake v. Dierdorff*, 856 F.2d 1365, 1368 (9th Cir.1988). Accordingly, the following allegations appear in the CC.

MannKind is a bio-pharmaceutical company and drug delivery technology company focused on the development and commercialization of therapeutic products for diabetes. (*Id.* ¶ 2.) The company's stock trades almost entirely on the prospects of its "lead product candidate," AFREZZA, an inhalable insulin product intended to treat adult patients with Type 1 and 2 diabetes. (*Id.*) In the parlance of the U.S. Food and Drug Administration ("FDA"), AFREZZA is a "combination drug product" because it works by combining a drug, a powderized form of human insulin, with a delivery device, a portable plastic inhaler. (*Id.*) Pfizer, Inc.'s prior inhalable insulin formulation, Exubera, received FDA approval but failed commercially and was pulled from the market because both doctors and patients rejected the awkward nature of the product's inhaler. (*Id.* ¶ 37.)

MannKind has spent over $1.5 billion developing AFREZZA, with the company's CEO, Alfred Mann, describing it as a potential "blockbuster" or "super blockbuster" product. (*Id.* ¶ 3.) MannKind has repeatedly struggled, however, to convince investors, analysts, and potential partners that AFREZZA would succeed where Exubera failed. (*Id.* ¶ 38.) Accordingly, it has long understood that AFREZZA would require an easy-to-use inhaler, and has focused substantial efforts on designing such a device. (*Id.* ¶ 39.)

***2** All of MannKind's "Phase III" trials, including those it designated as "pivotal" to showing the safety and efficacy of AFREZZA, involved a first-generation version of its inhaler design known as MedTone C. Although significantly smaller than the Exubera inhaler, MedTone C was still somewhat larger and sig-

nificantly more complex than most commercially-successful inhalation devices. (*Id.* ¶ 40.) But MannKind never sought approval of AFREZZA incorporating the MedTone C inhaler. (*Id.* ¶ 41.) Prior to the Class Period, MannKind's regulatory efforts focused on seeking approval of an incremental improvement of the first-generation MedTone C design, known as the MedTone D inhaler, which Defendant Mann once described as entailing "a moderate change in the design in order to make it more rugged and more manufacturable." (*Id.*) According to Plaintiffs, MannKind could not feasibly commercialize MedTone C AFREZZA because the device was flimsy, expensive to manufacture, and difficult to use. (*Id.* ¶ 4.)

MannKind could not secure approval of MedTone D AFREZZA unless it also proved to the FDA that the two inhaler versions—MedTone C and MedTone D—were "bioequivalent," meaning that they deliver the same "molar dose" of the drug's active ingredient into the site of action in the body. (*Id.* ¶ 42, 58.) In January 2009, Defendant Richardson conceded that MannKind had hoped to move forward with only *in vitro* proof of bioequivalence, but that the FDA had insisted on adding an *in vivo* clinical trial comparing the absorption of each version of AFREZZA in the bodies of actual diabetes patients. (*Id.* ¶ 32.) According to Plaintiffs, the FDA's insistence on a meaningful *in vivo* bioequivalency study was consistent with FDA regulations specifying that for drugs like insulin that act through systemic rather than local exposure, *in vivo* clinical trials are generally considered the most accurate, and are therefore required. (*Id.* ¶ 43.)

In March 2009, MannKind announced that it had submitted a New Drug Application ("NDA") to the FDA for approval of MedTone D AFREZZA based on a clinical program involving forty-four completed studies and five ongoing studies. (*Id.* ¶ 44.) In March 2010, however, the FDA sent MannKind a Complete Response Letter ("CRL") refusing to approve MedTone D AFREZZA on the basis of the March 2009 NDA. (*Id.* ¶ 45.) MannKind has never released the March 2010 CRL to investors, but has conceded that the FDA had continuing concerns regarding bioequivalence between MedTone C and MedTone D AFREZZA, apparently because MannKind chose to analyze the blood assays in the *in vivo* bioequivalency standard using a method the FDA believed to be inferior. (*Id.* ¶ 46.) Defendant Mann nevertheless assured investors in a March 2010 AFREZZA conference call that the deficiency would be addressed in a bioequivalency study for a next generation inhaler known as "Dreamboat." (*Id.*)

***3** Indeed, Mann announced in the March 2010 conference call that the company would be shifting regulatory approaches, abandoning MedTone D altogether and asking the FDA to approve "Dreamboat" AFREZZA when MannKind resubmitted an NDA. (*Id.* ¶ 48.) Dreamboat was much smaller than the MedTone inhalers, less complex, did not require disassembly or cleaning, was less costly to manufacture, was far more efficient, and was easier to operate. (*Id.* ¶ 51.) According to Plaintiffs, despite Defendants' assurances to investors that their midstream switch would actually help with regulatory approval, the radically different architecture, efficiency and functionality of Dreamboat AFREZZA made it more difficult to prove bioequivalence with MedTone C. (*Id.* ¶¶ 50–51.)

Thus, although AFREZZA has had some promising clinical results, MannKind was, during the relevant period, seeking regulatory approval for a version of the combination drug product that was not used in prior safety or efficacy trials. (*Id.*) Rather, the vast majority of its research had been conducted on an earlier version of the combination drug product, and MannKind's approval efforts relied upon convincing the FDA to accept clinical research for the earlier version of the product in support of the redesigned product it sought to commercialize. (*Id.*) Accordingly, every clinical trial designated as "pivotal" by MannKind, both in its original NDA in March 2009 and in its resubmitted NDA filed in July 2010, involved a version of AFREZZA consisting of 30U [2] of Technosphere insulin powder delivered using MannKind's MedTone C inhaler, rather than the smaller quantity delivered by Dreamboat. (*Id.* ¶ 4.)

Mann acknowledged in the March 2010 conference call that MannKind needed to "further discuss this approach with the FDA and confirm that we are aligned on what they would like to see and how they would like us to address the bridging between the inhaler that is ultimately launched and the inhaler that was used in the pivotal trials." (*Id.* ¶ 53.) According to Plaintiffs, however, Defendants never obtained such an agreement, and did not even base their subsequent comparative study on the face-to-face discussion with

the FDA. (*Id.* ¶ 54.) Rather, Defendants designed, enrolled test subjects, and conducted the bulk of their only human comparative study involving Dreamboat, known as Study 142, before even meeting with the FDA. (*Id.*) Despite understanding that bioequivalence was an open question as of March 2010, Defendants did not raise it with the FDA until June 9, 2010, when Study 142 was largely complete. (*Id.* ¶ 55.) According to Plaintiffs, the FDA never indicated to Defendants that Study 142 would constitute proof of bioequivalence, and Defendants, despite being able to do so, have not obtained or produced the minutes of their meeting with the FDA. (*Id.* ¶ 56.) Moreover, Plaintiffs allege, Study 142 was clinically flawed, and gave Defendants no legitimate reason to expect that the FDA would or could accept it as sufficient evidence of bioequivalence. (*Id.* ¶ 57.) The study was conducted on normal healthy individuals rather than diabetic patients and, as the FDA later stated, constituted merely a "pharmacology grid." (*Id.* ¶ 57.) In fact, according to Plaintiffs, Study 142 never purported to show that the same molar doses of Dreamboat AFREZZA and MedTone C AFREZZA delivered the same amount of insulin into the bloodstream, as required by the FDA's bioequivalency standards. (*Id.* ¶ 58.)

***4** According to Plaintiffs, after deciding to substitute the new Dreamboat inhaler in their 2010 NDA re-submission, Defendants mounted a "blitzkrieg-style public relations campaign to persuade investors that they would easily be able to establish bioequivalence, safety and efficacy with the new inhaler design." (*Id.* ¶ 60.) Over the next several months, MannKind sent its top executives to a number of investor conferences, at which Plaintiffs allege the materially false and/or misleading statements were made. (*Id.* ¶ 61.) Plaintiffs allege that CEO Mann even skipped a June 9, 2010 meeting with the FDA, "the most important meeting in the history of the Company," in order to court investors. (*Id.*)

The following statement is typical of the sort that Plaintiffs allege was materially false and/or misleading:

> As you know, we do have a new inversion inhaler.... We did recently complete the bioequivalence study. That was the so-called 142 study for the generation two device compared to the so-called Model C MedTone Inhaler, which is what we used in the Phase III pivotals. That study recently wrapped up and we did show bioequivalence. It's important to note that the study's design here was vetted with the FDA in advance. We got the blessing on the design last November for a fairly straightforward bioequivalence study.
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> ...
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> By clinical work, what we're talking about essentially is the bioequivalency study. Now, people seem confused by that sometimes, so I guess I should elaborate on that because typically if you have a lung delivered product, it's difficult to do bioequivalency studies. That's because most of those products are topical lung products. In this instance, this is something we can do just with a simple blood test.

(*Id.* ¶ 63.) Plaintiffs allege that statements such as these were materially false and/or misleading when made because, among other things, Study 142 was not a "bioequivalency study," and did not "show bioequivalence" due to a number of methodological errors Defendants knew about; and because Study 142 was never "vetted" or "bless[ed] by the FDA as a means of establishing bioequivalence, as evidenced by the FDA's later wholesale rejection of such studies, as well as the inference that the FDA would not agree to accept as sufficient a specific method of establishing bioequivalency that it later found to be inadequate. (*Id.* ¶ 64.)

Plaintiffs recite in full a number of other statements made by Defendants in the ensuing months. Among these are Defendant Pfeffer's on June 9, 2010: "We did complete our bioequivalence study ... and that was successful, we did show bioequivalence in that study. It was designed based on FDA recommendations and that was a relief to some people" (*Id.* ¶¶ 70–71); Defendant Richardson's and Mann's on June 24, 2010: "But in terms of where we are with the response to the [CRL], there were three areas which I think we've shared very clearly in terms of that ... the question of efficacy really isn't there" (*Id.* ¶¶ 72–73); Defendant Richardon's on August 2, 2010: "we've met the FDA established definition [of bioequvialence] using two well validated assays as agreed with the Agency. Study 142 has demonstrated the inhalation system used in the Phase 3 trials and generation 2 inhalation system to be bioequivalent" (*Id.* ¶¶ 76–77);

Defendant Pfeffer's on August 11, 2010: "We did [receive a CRL]—we were able to announce the results, and you can see slides and detailed information about our bioequivalence study. This is in keeping with an agreement we've made with the FDA for how to change from one inhaler to the next" (*Id.* ¶¶ 78–79); and Defendant Mann's on September 15, 2010: "[The FDA has] accepted all the bioequivalency and handling studies we did. They have accepted the re-submission with the new device.... We demonstrated that the amount of insulin going into the lungs and to the blood are identical. They are very comfortable with that." (*Id.* ¶¶ 86–87.)

***5** On August 11, 2010, MannKind announced a unique financing arrangement with a private investment partnership, Seaside 88, LP ("Seaside"), under which Seaside agreed to buy up to 18,200,000 shares of MannKind stock in tranches of 700,000 every other week, for 52 weeks, provided that MannKind was trading above $6.50 per share. (*Id.* ¶ 80.) According to Plaintiffs, the agreement had the potential to bring in over $100 million in capital if MannKind was able to keep its share price above $6.50. (*Id.*) At the same time, MannKind announced that CEO Mann had agreed to convert a portion of the debt the company owed him into an equal amount of shares to those bought by Seaside in each tranche, giving the company access to another $100 million. (*Id.*) One analyst who took note of the deal wrote that the agreement could fund MannKind's operations beyond year-end 2011, and that the deal would provide the company with an improved bargaining position with potential partners. (*Id.* ¶ 81.)

On November 4, 2010, MannKind disclosed that John Arditi, then Senior Worldwide Director of Regulatory Affairs, had filed a lawsuit alleging potential fraud and scientific misconduct in at least two Eastern European clinical sites tainting data that MannKind had submitted to the FDA as part of its NDA. (*Id.* ¶ 90.) Arditi alleged that he had warned Patricia Meyer, MannKind's Vice President of Regulatory Affairs, that MannKind employees had confirmed audit concerns regarding potential fraud and scientific misconduct in connection with various trials and studies and reports derived therefrom. (*Id.* ¶ 91–95.) Plaintiffs allege that MannKind had concealed these problems from both investors and the FDA for over a year, despite the fact that they indicated problems with the data submitted to the FDA. (*Id.* ¶ 96.) Moreover, when MannKind did disclose the Arditi lawsuit, the press release omitted that the FDA would have to investigate the accusations, likely delaying approval even if MannKind's 2010 NDA re-submission was not deficient. (*Id.* ¶ 97.)

On December 28, 2010, MannKind issued a press release announcing that the company had received notification from the FDA that it was unable to complete review of the NDA for AFREZZA by December, 2010, and would require an additional four weeks to complete its review. (*Id.* ¶ 98.) On January 12, 2011, Defendant Mann stated at a JP Morgan Healthcare Conference that "AFREZZA addresses [the] market. We think it's a blockbuster or even super blockbuster potential.... We've studied this in an enormous number of trials, over 50 trials, well over 5,000 patients and we've not seen a single safety signal." (*Id.* ¶ 99.) Defendants' stock price rose from $8.71 per share to $9.40 per share from January 11, 2011 to January 13, 2011. (*Id.*)

On January 18, 2011, MannKind received a second CRL notifying it that the FDA had refused to approve AFREZZA on the basis of its 2010 NDA re-submission, and requesting that the company undertake two lengthy and expensive Phase III clinical trials with the new inhaler, adding an additional arm or cohort to one of the two trials utilizing MedTone C AFREZZA. (*Id.* ¶ 103.) While MannKind waited until the following day to disclose this information, the company's stock continued to trade above $10 per share on January 18, 2011. (*Id.* ¶ 103.) On that same day, January 18, 2011, Defendant Pfeffer, the company's CFO, sold 6,300 shares of his own MannKind stock for $10.00 per share. (*Id.* ¶ 104.)

***6** Rumors of the second CRL leaked into the market on January 18, 2010 and January 19, 2010. (*Id.* ¶ 105.) Trading was halted around noon on January 19, 2011, and remained halted for the rest of the day. (*Id.*) MannKind then issued a press release acknowledging the FDA's issuance of a second CRL, highlighting certain deficiencies identified by the FDA. (*Id.* ¶ 106.) On a conference call that day, CEO Mann stated that "[t]he FDA noted that we attempted to rely on in vitro performance data, and a clinical pharmacology grid to the Phase 3 trials conducted with the MedTone inhaler, but indicated that this approach was iandequate." (*Id.* ¶ 107.) When shares resumed trading on January 20, 2011, MannKind's stock plunged over $4 to reach an intra-day low of $5.00, before re-

bounding slightly to close at $6.17 per share. (*Id.* ¶ 109.) Over the next few days, the share price fell to the $5.00–5.50 range. (*Id.*) On February 10, 2011, MannKind announced that the costs and delays resulting from the FDA's second CRL would be substantially worse than acknowledged earlier, and MannKind's shares dropped to $3.79. (*Id.* ¶ 110.)

Plaintiffs subsequently brought this securities fraud class action on behalf of all persons who purchased or otherwise acquired MannKind common stock during the Class Period, alleging violations of § 10(b) of the Exchange Act and Rule 10b–5 as promulgated thereunder, as well as § 20(a) of the Exchange Act. (*Id.* ¶¶ 119–134.) Plaintiffs also attach the report of purported expert Dr. Guarino, President of Oxford Pharmaceutical Resources, Inc., a consulting service for pharmaceutical companies. The report is used primarily to (1) demonstrate that it would be a deviation from standard FDA practice to reach an unenforceable agreement with MannKind as to bioequvialency methodology, or to pre-approve a methodology that the Agency would later reject; and (2) that the bioequivalency methodology used was woefully inadequate.

On August 12, 2011 Defendants filed the pending motions to dismiss and to strike the expert report from Plaintiffs' complaint. (Docket Nos. 58, 59.)

III. DISCUSSION

A. MOTION TO DISMISS

To state a claim under § 10(b) of the Exchange Act, Plaintiff must allege (1) a material misstatement or omission; (2) scienter; (3) connection with the purchase or sale of a security; (4) reliance; (5) proximate or "loss" causation; and (6) economic loss. *Dura Pharmaceuticals, Inc. v. Broudo*, 544 U.S. 336, 341, 125 S.Ct. 1627, 161 L.Ed.2d 577 (2005).

Plaintiffs point to a number of statements made by Defendants during the Class Period that they allege were materially false and made with scienter. Defendants contend that these purported misstatements are inadequate to plead the falsity, scienter, and loss causation elements of a § 10(b) claim, and are not actionable under the Private Securities Litigation Reform Act ("PSLRA"). The Court examines these statements in turn.

1. LEGAL STANDARDS UNDER FEDERAL RULES OF CIVIL PROCEDURE 12(B)(6) AND 9(B), AND THE PSLRA

***7** A complaint may be dismissed if it fails to state a claim upon which relief can be granted. *See* Fed.R.Civ.P. 12(b)(6). On a motion to dismiss under Rule 12(b)(6), a court must accept as true all factual allegations pleaded in the complaint, and construe them "in the light most favorable to the nonmoving party." *Cahill v. Liberty Mut. Ins. Co.*, 80 F.3d 336, 337–38 (9th Cir.1996) Dismissal under Federal Rule of Civil Procedure 12(b)(6) may be based on either (1) a lack of a cognizable legal theory, or (2) insufficient facts under a cognizable legal theory. *SmileCare Dental Grp. v. Delta Dental Plan of Cal., Inc.*, 88 F.3d 780, 783 (9th Cir.1996) (citing *Robertson v. Dean Witter Reynolds, Inc.*, 749 F.2d 530, 534 (9th Cir.1984)).

Under Federal Rule of Civil Procedure 8(a)(2), a complaint must contain "a short and plain statement of the claim showing that the pleader is entitled to relief." Fed.R.Civ.P. 8(a)(2). The Supreme Court has interpreted this rule to allow a complaint to survive a motion to dismiss only if it "contain[s] sufficient factual matter, accepted as true, to 'state a claim to relief that is plausible on its face.' " *Ashcroft v. Iqbal*, 556 U.S. 662, 129 S.Ct. 1937, 1949, 173 L.Ed.2d 868 (2009) (quoting *Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 570, 127 S.Ct. 1955, 167 L.Ed.2d 929 (2007)). "A claim has facial plausibility when the plaintiff pleads factual content that allows the court to draw the reasonable inference that the defendant is liable for the misconduct alleged." *Id.* (citing *Twombly*, 550 U.S. at 556). "[W]here the well-pleaded facts do not permit the court to infer more than the mere possibility of misconduct," the complaint has not sufficiently established that the pleader is entitled to relief. *Id.* at 1950.

While a complaint generally need not contain detailed factual allegations, "a plaintiff's obligation to provide the grounds of his entitlement to relief requires more than labels and conclusions, and a formulaic recitation of the elements of a cause of action will not do." *Twombly*, 550 U.S. at 555 (citation, alteration, and internal quotation marks omitted). Similarly, a court need not "accept as true allegations that are merely conclusory, unwarranted deductions of fact, or unreasonable inferences." *Sprewell v. Golden State Warriors*, 266 F.3d 979, 988 (9th Cir.2001). In other words, "the tenet that a court must accept as true

all of the allegations contained in a complaint is inapplicable to legal conclusions.... While legal conclusions can provide the framework of a complaint, they must be supported by factual allegations." *Iqbal*, 129 S.Ct. at 1949–50.

Moreover, Federal Rule of Civil Procedure 9(b) imposes heightened pleading requirements for claims of fraud. *See* Fed.R.Civ.P. 9(b). Under Rule 9(b), a plaintiff "must state with particularity the circumstances constituting fraud," but can allege generally "[m]alice, intent, knowledge, and other conditions of a person's mind." *Id.* The particularity requirement "has been interpreted to mean the pleader must state the time, place and specific content of the false representations as well as the identities of the parties to the misrepresentation." *Miscellaneous Serv. Workers, Drivers & Helpers, Teamsters Local No. 427 v. Philco–Ford Corp.*, 661 F.2d 776, 782 (9th Cir.1981). Further, where there are multiple defendants, "Rule 9(b) does not allow a complaint to ... lump multiple defendants together but require[s] plaintiffs to differentiate their allegations when suing more than one defendant." *Destfino v. Reiswig*, 630 F.3d 952, 958 (9th Cir.2011) (citation and internal quotation marks omitted). In addition, the plaintiff must "set forth what is false or misleading about a statement, and why it is false." *Rubke v. Capitol Bancorp Ltd.*, 551 F.3d 1156, 1161 (9th Cir.2009) (internal quotations omitted). These requirements "ensure ... that allegations of fraud are specific enough to give defendants notice of the particular misconduct which is alleged to constitute the fraud charged so that they can defend against the charge and not just deny that they have done anything wrong." *Semegen v. Weidner*, 780 F.2d 727, 731 (9th Cir.1985).

***8** Beyond the requirements of Fed.R.Civ.P. 12(b)(6) and 9(b), the PSLRA establishes even higher pleading standards a plaintiff must meet when alleging a securities fraud cause of action. These requirements pertain largely to the "scienter" and "falsity" inquiries, which the Court addresses below.

2. STATEMENTS CONCERNING FDA'S PRE–APPROVAL OF BIOEQUIVALENCE STUDIES

Plaintiffs first cite to statements in which defendants seek to assure investors that the FDA had pre-approved the methodology utilized in their bioequivalence studies, or reached an "agreement" with Defendants as to how those studies were to be conducted. (CC ¶¶ 63, 65, 70, 76, 78, 86.) Plaintiffs allege that such statements were "materially false and/or misleading when made, and made with scienter, because Defendants knew or should have known that" the study and/or its methodology had not been pre-approved by the FDA, and that no "agreement" had ever been reached with the FDA concerning the way to conduct those studies. (*Id.* ¶¶ 64, 68, 77, 79, 87). A number of these statements are reproduced below.

On May 4, 2010, at a Deutsche Bank healthcare investors conference, Defendant Pfeffer stated:

> As you know, we do have a new inversion inhaler. That was the one you saw on the slide. We did recently complete the bioequivalence study. That was the so-called 142 study for the generation two device compared to the so-called Model C MedTone Inhaler, which is what we used in the Phase III pivotals. That study recently wrapped up and we did show bioequivalence. ***It's important to note that the study's design here was vetted with the FDA in advance. We got the blessing on the design last November for a fairly straightforward bioequivalence study.***

(*Id.* ¶ 63) (emphasis added). Defendant Mann, on May 12, 2010, at a Bank of America healthcare investors conference, stated:

> ***In getting the new inhaler approved, [the FDA] already approved the protocol for it, and we have completed all the elements of the protocol and that will be submitted along with it.*** The 142 showed very good bioequivalency, not an issue at all.

(*Id.* ¶ 65) (emphasis added). During a question and answer session, Mann further stated:

> <Q> ... Just so I understand where you are with the FDA, you mentioned that they don't require any new clinical studies? Do you have a sense with them on the new device whether they could come back and request new clinical trials specifically with the new device or did you already have discussions previously when you did your bioequivalency studies?
>
> <A> Well, what we did is about a year ago, we went to them and said we've made such progress in this new device that we would like to bridge to this device. And we would like to have a meeting with you

> to discuss how to get there? And they said, send us a briefing book and a proposed protocol, and we'll come back to you, in writing. And so they came back to us finally and we started this thing. There were four elements to the protocol, they've all been completed, although because of the question they raised about the insulin assay methodology, we are doing it both ways and doing it their way, still another couple of weeks to go. But it will be done in time to submit it easily with our response to the CRL.

***9** (*Id.*) On August 2, 2010, MannKind held a second quarter 2010 earnings conference call, on which Defendant Richardson stated:

> Because there has been considerable interest in bioequivalence, I will go over in some detail results of these studies, showing that we've met the FDA ***established definition using two well validated assays as agreed with the Agency.*** Study 142 has demonstrated the inhalation system used in the Phase 3 trials and generation 2 inhalation system to be bioequivalent.

(*Id.* ¶ 76.) On August 11, 2010, at a Cannacord Adams growth investors conference, Defendant Pfeffer stated:

> We did receive a complete response letter earlier in the year, but managed to get back on file fairly quickly because we found the issues they raised relatively easily addressable by us.
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> ...
>
> We did—we were able to announce the results, and you can see slides and detailed information about our bioequivalence study. ***This is in keeping with an agreement we've made with the FDA for how to change from one inhaler to the next ....***

(*Id.* ¶ 78) (emphasis added). Finally, on September 15, 2010, at a Rodman & Renshaw healthcare investors conference, Defendant Mann stated:

> [The FDA] ha[s] accepted all the bioequivalency and handling studies we did. They have accepted the re-submission with the new device.
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> ...
>
> We demonstrated that the amount of insulin going into the lungs and to the blood are identical. They are very comfortable with that.

(*Id.* ¶ 86.)

Plaintiffs argue that at the time these statements were made, the FDA had not, in fact, accepted or "agreed" to any of MannKind's bioequivalency or handling studies, nor was the FDA "very comfortable" with the protocol utilized by MannKind in those studies. (CC ¶ 87.)

a. Scienter

To demonstrate scienter, the PSLRA requires that a plaintiff "state with particularity facts giving rise to a strong inference that the defendant acted with the required state of mind" in making misleading statements and/or omissions. 15 U.S.C. § 78u–4(b)(2). "Under this provision, the mental state required for securities fraud liability is distinct from the level of pleading required to infer that mental state." *South Ferry*, 542 F.3d at 782 (quoting *Silicon Graphics*, 183 F.3d at 975). Plaintiffs must show that Defendants "engaged in 'knowing' or 'intentional' conduct." *South Ferry*, 542 F.3d at 782. In the Ninth Circuit, "reckless conduct can almost meet this standard to the extent that it reflects some degree of intentional or conscious misconduct, or what [courts] have called 'deliberate recklessness.' " *Id.* (citing *Silicon Graphics*, 182 F.3d at 977) (quotation marks omitted). Thus, in sum, a complaint must state with particularity facts giving rise to a strong inference of "deliberate recklessness" in order to satisfy the PSLRA's pleading requirements for scienter.

The Supreme Court has held that this "strong inference" must be "cogent and compelling, [and] thus strong in light of other explanations." *Tellabs, Inc. v. Makor Issues and Rights, Ltd.*, 551 U.S. 308, 324, 127 S.Ct. 2499, 168 L.Ed.2d 179 (2007). The reviewing court must ask, "when the allegations are accepted as true and taken collectively, would a reasonable person deem the inference of scienter a least as strong as any opposing inference?" *Id.* at 326. In other words, "[a] court must compare the malicious and innocent inferences cognizable from the facts pled in the complaint, and only allow the complaint to survive a motion to dismiss if the malicious inference is at least as compelling as any opposing innocent inference." *Zucco Partners*, 552 F.3d at 991. "The court must determine whether 'all of the facts alleged, taken

collectively, give rise to a strong inference of scienter, not whether any individual allegation, scrutinized in isolation, meets that standard.' " *Id.* (quoting *Tellabs*, 551 U.S. at 323); *see also South Ferry*, 542 F.3d at 784 ("The Supreme Court's reasoning in *Tellabs* permits a series of less precise allegations to be read together to meet the PSLRA requirement.")

***10** Moreover, with respect to falsity, the complaint must "specify each statement alleged to have been misleading, the reason or reasons why the statement is misleading, and, if an allegation regarding the statement or omission is made on information and belief, the complaint shall state with particularity all facts on which that belief is formed." 15 U.S.C. § 78u–4(b)(1).

The scienter and falsity inquiries overlap significantly. In *Ronconi v. Larkin*, the Ninth Circuit explained that:

> Because falsity and scienter in private securities fraud cases are generally strongly inferred from the same set of facts, we have incorporated the dual pleading requirements of 15 U.S.C. §§ 78u–4(b) (1) and (b)(2) into a single inquiry. In considering whether a private securities fraud complaint can survive dismissal under Rule 12(b)(6), we must determine whether "particular facts in the complaint, taken as a whole, raise a strong inference that defendants intentionally or with 'deliberate recklessness' made false or misleading statements to investors."

253 F.3d 423, 429 (9th Cir.2001) (quoting *In re Silicon Graphics Inc. Securities Litigation*, 183 F.3d 970, 979 (9th Cir.1999)). The Ninth Circuit recently re-iterated that "falsity may itself be indicative of scienter where it is combined with allegations regarding a management's role in the company that are particular and suggest that the defendant had actual access to the disputed information, and where the nature of the relevant fact is of such prominence that it would be absurd to suggest that management was without knowledge of the matter." *Zucco Partners, LLC v. Digimarc Corp.*, 552 F.3d 981, 1000 (9th Cir.2009) (quotation marks and citation omitted) (quoting *South Ferry LP, No. 2 v. Killinger*, 542 F.3d 776, 785 (9th Cir.2008)).

Plaintiffs base their allegation of scienter here primarily "on defendants' actual knowledge of facts that demonstrate the falsity of their misstatements." (Docket No. 63, Opp. at 17.) Plaintiffs also allege certain facts they contend provide a motive for Defendants' making of such statements. The Court will examine these allegations in turn.

i. Falsity

The Court finds that Plaintiffs have made a sufficient showing of scienter with regard to these statements, as they have adequately pleaded facts showing a "strong inference that defendants intentionally or with 'deliberate recklessness' made false or misleading statements to investors." *Ronconi*, 253 F.3d at 429. When considered against other, competing inferences that may be drawn from the allegations found in the complaint, these representations are best read as a misstatement of the basic facts regarding the company's ongoing involvement with the FDA, and thus the likelihood of AFREZZA approval.

Plaintiffs base their contention that these statements were false and known to be so when made on three pieces of circumstantial evidence: (1) Defendants' later characterization of the FDA's communications with MannKind as mere "advice," a description inconsistent with their prior statements describing an "agreement or "approval" (Opp. at 14); (2) the common sense inference that the FDA would not "approve," "bless" or "agree to" that which it would reject several months later; and (3) the expert report of Dr. Guarino, which buttresses this second inference with purportedly expert opinion, confirming that "the FDA does not agree to accept 'as sufficient a specific method of proving bioequivalency, and then declare that same method to be 'insufficient,' " and that "if indeed there was an agreement, it would have been memorialized in writing and would have been enforceable against the FDA." (CC ¶ 64(b); Opp. at 13.) In particular, Plaintiffs point to Defendant Mann's statement, after receipt of the 2011 CRL, that "the FDA noted that we attempted to rely on *in vitro* performance data, and a clinical pharmacology grid to the Phase 3 trials conducted with the MedTone inhaler, but indicated that this approach was inadequate," which Plaintiffs contend "directly contradict[s] Defendants' assurances during the Class Period that the FDA had 'bless[ed],' 'vetted,' 'approved,' 'accepted,' and 'agree[d]' to the same approach." (CC ¶ 107).

***11** In their motion, Defendants lay heavy em-

phasis on the fact that in demonstrating falsity, Plaintiffs rely in part upon the FDA's 2011 CRL to demonstrate that no such "agreement" or "blessing" existed, calling this classic fraud-by-hindsight pleading. (Docket No. 59, Mem. at 18.) Defendants' argument misses the mark. Fraud is almost always detected after the fact, typically based on evidence developed subsequent to the allegedly fraudulent statements. Courts must of course be careful to distinguish between forward-looking statements later deemed to be unduly optimistic, and statements of historical fact later shown to be *false* when made. The statements that the FDA had accepted, or blessed, or agreed to the Defendants' bioequivalency methodology—which are shown to be false by a later revelation demonstrating that the FDA had not, in fact, done any such thing—do not constitute "fraud-by-hindsight," as Defendants repeatedly allege.[FN1]

> FN1. Moreover, as noted above, Plaintiffs do not rely solely on the "hindsight" provided by the FDA's later rejection of such studies; rather, they point to later statements by Defendants acknowledging that the FDA had merely given "advice" concerning bioequivalency. (Opp. at 14.)

Indeed, Defendants' generic and misplaced characterization of Plaintiffs' complaint does not in any way rebut the allegations that Defendants' statements were made with deliberate recklessness as to their veracity. Defendants do not in their papers even offer an explanation of these statements, other than to contend that the FDA technically "accepted" the NDA *submission*, and thus could not have viewed the studies as glaringly insufficient. (Docket No. 67, Reply at 11.) At the hearing on this motion, Defendants, for the first time, sought to articulate an alternative interpretation of the facts Plaintiffs allege concerning the supposed "agreement" with or "vetting" by the FDA. Based on various statements by Defendants characterizing the contents of the 2011 CRL, Defendants suggest that the response letter was not addressing or rejecting Defendants' bioequivalence studies, but rather merely requesting additional clinical trials on pulmonary function, an unrelated matter. Responding to that characterization, Plaintiffs argued that the fairer interpretation of the 2011 CRL is that the FDA did in fact reject Defendants' bioequvialence studies, and, because Defendants' submission now resided outside the regulatory definition of bioequivalence, ordered clinical trials as a *substitute* for that failure.

Defendants' belated articulation of an alternative reading of the facts pleaded in the complaint brings this case directly within the Supreme Court's *Tellabs* inquiry. As noted above, the *Tellabs* inquiry entails a "compar [ison] [of] the malicious and innocent inferences cognizable from the facts pled in the complaint," under which the complaint survives a 12(b)(6) motion only if "a reasonable person [would] deem the inference of scienter at least as strong as any opposing inference." *Zucco*, 552 F.3d at 991; *Tellabs*, 551 U.S. at 326.

On the basis of the record before it, the Court cannot conclude that Defendants' new and unsubstantiated reading of the facts is any more compelling than Plaintiffs' proposed interpretation. Defendants made a series of statements in which they described the FDA's "vetting" of, "blessing" of, "approval" of, and "agreement" with their bioequivalency studies. Based on the FDA's subsequent ordering of further studies, the Court finds that the most plausible inference to draw is that Defendants' showing of bioequivalence had failed, and that no "agreement" or "blessing" had ever been secured. Defendants' own 10–K buttresses this interpretation when it specifically states that "the principal issue raised by the FDA in the January 2011[CRL] was the usage of *in vitro* performance data and bioequivalence data to bridge our next-generation inhaler to the Phase 3 trials conducted using the MedTone (model C) inhaler." (Docket No. 59–2, Declaration of Koji K. Fukumura ("Fukumura Decl."), Ex. A [Form 10–K 2010] at 27.) Although Defendants contend that such statements do not establish that the FDA ever disapproved of the bioequivalency studies *themselves*, the Court finds that Plaintiffs' reading, namely that Defendants had failed to establish bioequivalence, and thus had to conduct additional clinical trials, is at least as compelling.

***12** Moreover, Plaintiffs present a wide array of evidence that Defendants' bioequivalency studies were inadequate to make the sort of showing required by the FDA. Although the Court concludes below that these statements concerning the *merits* of the bioequivalency studies do not alone demonstrate scienter, they do lend support to Plaintiffs' reading of the 2011 CRL, namely that bioequivalence had not been established.[FN2] Plaintiffs' expert report buttresses these

inferences, confirming that the Defendants' proposed reading of the 2011 CRL would be at odds with standard FDA practice.

> FN2. Given competitive concerns, Defendants have never disclosed the CRLs, and so Plaintiffs must rely in part upon inference in order to reconstruct what these letters likely contained. Defendants repeatedly fault Plaintiffs for not being able to conclusively demonstrate that the statements concerning the FDA's "blessing," "pre-approval," and so on were false. But based on the Court's discussion above, this is the most plausible inference to draw from the complaint, which is all that *Tellabs* requires. The contents of these CRLs, however, would presumably go a long way in resolving the parties' claims.

Accordingly, while Mann's statement that the company had "demonstrated that the amount of insulin going into the lungs and to the blood are identical," along with other statements touting the *merits* of the bioequivalency studies, can be fairly read as misguided opinion or "corporate optimism," it is harder to escape the conclusion that Defendants' statements concerning the FDA cross the line from exaggeration and "corporate optimism" into outright misstatement of historical fact. While Defendants seek to blur the line between an "agreement" or "approval" on the one hand, and mere "discussions" and "recommendations" on the other, and contend that such a distinction is insufficient to support a finding of scienter, the case law only requires a showing that Defendants spoke with "deliberate recklessness" as to the truth of their statements. The Court finds that Plaintiffs have made a compelling showing that Defendants did just that.

Indeed, case law addressing misstatements relating to FDA approval lends support to Plaintiffs' use of these statements to demonstrate scienter. "When the FDA tells a company about the problems with a product, and the company nonetheless continues to make confident statements about the product, courts have inferred scienter and falsity." *Construction Laborers Pension Trust of Greater St. Louis v. Neurocrine Biosciences, Inc.*, 2008 WL 4370010, at *4 (S.D.Cal. Sep.23, 2008) (citing *Yanek v. Starr Surgical Co.*, 388 F.Supp.2d 1110, 1130 (C.D.Cal.2005) ("These statements necessarily implied that there would be no serious impediments to timely FDA approval. Thus, Defendants' omission of facts suggesting a possible delay in approval was misleading.")) *See also In re Dura Pharmaceuticals, Inc. Securities Litigation*, 548 F.Supp.2d 1126 (S.D.Cal.2008) (finding materially false statements that failed to explain that the FDA was requiring submission of new clinical data in letter of rejection); *In re Immune Response Securities Litigation*, 375 F.Supp.2d 983 (S.D.Cal.2005) (finding sufficient for purposes of scienter inquiry misstatements about likelihood of FDA approval given methodological weaknesses in clinical studies).

As in *Yanek*, Defendants' statements concerning "approval" and "blessing" by the FDA "necessarily implied that there would be no serious impediments to timely FDA approval." The natural effect of these statements would be to create the impression for investors that, as Plaintiffs characterized it at the hearing, "it was in the bag"—that there was a minimal chance of failure because the bioequivalence studies had been specifically approved or agreed to by the very agency that would be reviewing them. As evidenced by the stock's precipitous drop following the 2011 CRL, Defendants' representations concerning AFREZZA's chances at FDA approval and the intricacies of the process were the essential underpinning of the company's share price. In short, FDA approval was the *sina qua non* for MannKind Corporation's success, and statements pertaining to the chances of such approval and the speed with which it would be secured were absolutely essential to the company's prospects. Accordingly, Defendants' statements concerning an "agreement" with the FDA, or the FDA's pre-approval or "blessing" of their bioequivalency studies were extremely important to investors, and, therefore, extremely misleading.

***13** The Court therefore finds that, taken alone, Defendants' statements concerning "approval" by or an "agreement" with the FDA are sufficient to demonstrate a strong inference of scienter.

ii. Motive

The Supreme Court has recently stated that, with regard to "a strong inference of scienter":

> While it is true that motive can be a relevant consideration, and personal financial gain may weigh heavily in favor of a scienter inference, we agree with the Seventh Circuit that the absence of a mo-

> tive allegation is not fatal. As earlier stated, allegations must be considered collectively; the significance that can be ascribed to an allegation of motive, or lack thereof, depends on the entirety of the complaint.
>
> *Tellabs*, 551 U.S. at 325 (citations omitted).

As noted above, Plaintiffs state that "scienter is alleged [here] based on defendants' actual knowledge of facts that demonstrate the falsity of their misstatements." (Opp. at 17.) Despite this, and despite the fact that scienter can be established solely from "deliberately reckless" falsity, Plaintiffs point to two possible motivations Defendants might have had in issuing the allegedly false statements: (1) maintenance of a particular financing arrangement; and (2) Defendant Pfeffer's sale of stock at artificially inflated prices shortly before the market became aware of the FDA's 2011 CRL.

(1) Financing

First, Plaintiffs point to the financing arrangement MannKind reached with Seaside, under which Seaside agreed to buy up to 18,200,000 shares of MannKind stock so long as it was trading above $6.50 per share. (CC ¶ 80.) As Plaintiffs point out, the agreement "had the potential to bring in well over $100 million in capital but only if MannKind was able to keep its shares propped above $6.50." (*Id.*) Moreover, "[s]imultaneous with the Seaside deal, MannKind announced that Mann agreed to convert a portion of the massive debt the Company owed him into an equal amount of shares to those bought by Seaside in each tranche," raising the value of the deal to over $200 million. (*Id.* ¶ 80.) Plaintiffs point to a Wells Fargo analysts' note that "the agreement could fund operations beyond year-end 2011" and "improve[ ] [MannKind's] bargaining position with potential partners." (*Id.* ¶ 81.) Thus, Plaintiffs reason, Defendants had a strong financial incentive to keep their share price artificially inflated throughout the Class Period, lest they lose access a key financing arrangement. (*Id.* ¶ 127.)

Defendants cite to a series of district court cases holding that "the generic motive of increasing capital is not enough" to support a strong inference of scienter, as otherwise "virtually every company in the United States that experiences a downturn in stock price would be forced to defend against actions for securities fraud." *In re PetSmart, Inc. Securities Litigation*, 61 F.Supp.2d 982, 998–999 (D.Ariz.1999) (collecting cases) (quotation marks omitted); *see also Lipton v. Pathogenesis Corp.*, 284 F.3d 1027, 1038 (9th Cir.2002) ("If scienter could be pleaded merely by alleging that officers and directors possess motive and opportunity to enhance a company's business prospects, 'virtually every company in the United States that experiences a downturn in stock price could be forced to defend securities fraud actions.' ") (citation omitted).

***14** Other district courts in this circuit, however, have found that an allegation that "defendants were motivated to inflate artificially [their company's] stock price *in the short term ... and obtain much-needed operating capital* does allege facts of a palpable motive for fraud," as it goes beyond "the generic desire to raise capital which can be attributed to every company." In *re Portal Software, Inc. Securities Litigation*, 2005 WL 1910923, at * 12 (N.D.Cal. Aug.10, 2005) (emphasis added) (quotation marks and citations omitted); *see also WPP Luxembourg Gamma Three Sarl v. Spot Runner, Inc.*, 655 F.3d 1039, 1052 (9th Cir.2011) ("continued infusion of investment capital" when company had minimal operating income one consideration in fraudulent intent inquiry).

Accordingly, Defendants' short-term need to keep their stock price above $6.50 per share provides a plausible motive for Defendants' actions, and supports a finding of scienter. On the basis of the CC, Defendants' motive to artificially inflate the company's stock price stems not merely from the "generic desire" to raise capital, but also from a need to keep the share price above a particular level in order to maintain access to much-needed operating capital. As in *WPP Luxembourg*, the Court finds that such motive evidence buttresses a finding of scienter.

(2) Sale of Stock

Plaintiffs also point to Defendant Pfeffer's January 18, 2011 sale of 6,300 shares of MannKind stock as evidence of a motive to commit fraud. (CC ¶ 103.) January 18, 2011 is the same day that MannKind received the second CRL from the FDA, notifying it that the Agenwas refusing to approve AFREZZA on the basis of its 2010 NDA resubmission, and requesting that the company undertake additional clinical trials with the new inhaler. (*Id.*) The company waited until the following day, January 19, to disclose

this information, and the stock continued to trade above $10 per share on January 18. (*Id.*) Accordingly, Plaintiffs reason, Pfeffer, the company's CFO, "was motivated to make the false and misleading statements complained of ... by the personal financial gains he made by selling MannKind shares at inflated prices, including 6,300 shares on the day that MannKind received—but did not diclose—the CRL rejecting Dreamboat AFREZZA." (*Id.* ¶ 129.)

These allegations do not provide strong support for a finding of scienter under the applicable case law. " 'Suspicious' stock sales by corporate insiders are circumstantial evidence of intent to defraud." *Silicon Graphics*, 183 F.3d at 1001 (citing *In re Apple Computer Sec. Litig.*, 886 F.2d 1109, 1117 (9th Cir.1989)). However, in a securities fraud action, allegations of such stock sales are "suspicious only when [they are] dramatically out of line with prior trading practices at times calculated to maximize the personal benefit from undisclosed inside information." *Ronconi*, 253 F.3d at 435 (citing *Silicon Graphics*, 183 F.3d at 986) (quotation marks omitted). In assessing the relative "suspiciousness" of a stock sale, the Ninth Circuit has "identified three relevant factors: (1) the amount and percentage of shares sold by insiders; (2) the timing of the sales; and (3) whether the sales were consistent with the insider's prior trading history." *Id.* (quoting *Silicon Graphics*, 183 F.3d at 986). Courts have generally been hesitant to find such sales suspicious. *See Silicon Graphics*, 183 F.3d at 987 (finding sales of 2.6 to 6.9 percent not suspicious, and 43.6–75.3 percent "somewhat suspicious," but insufficient to give rise to a strong inference of deliberate recklessness because stock sold made up insignificant portion of total allegedly suspicious sales); *see also PetSmart*, 61 F.Supp.2d at 1000 (collecting cases finding 11% of holdings insufficient, and holding that "where an individual retained more shares than he or she sold, ... resulting aggregate loss will defeat an inference of fraud.")

***15** Defendants seek to put the sale "in context" by pointing out that Defendant Pfeffer sold only 10.5% of his then-vested holdings, and that the sale was made pursuant to a pre-determined 10b5–1 trading plan, and was identical to another 10b5–1 trading sale made 11 months earlier. (Mem. at 15.) Although the timing of the sale appears suspicious, Plaintiffs do not rebut Defendants' contention that it was pre-determined pursuant to a 10b5–1 plan. Accordingly, the Court finds that Defendant Pfeffer's sale of stock does not provide support for Plaintiffs' pleading of scienter.

iii. Access to Information

Defendants' purported access to certain information contradicting their public statements provides additional support for finding a "strong inference" of scienter. Plaintiffs allege that the "above-identified materially false and/or misleading representations went to Defendants' core operations, and were contrary to information known by and/or available to but recklessly disregarded by Defendants." (CC ¶ 101.) In support of that assertion, Plaintiffs point out that "AFREZZA was MannKind's only advanced-stage product"; that it was "by an overwhelming margin the most important product in the Company"; and that "[o]btaining approval for AFREZZA, including establishing bioequivalence ... was understood by Defendants to be of paramount importance." (*Id.*) Plaintiffs further allege that Defendants had access to various information that contradicted their public representations, including "access to the true facts from" their meetings and various other communications with the FDA, including those communications concerning the supposedly "collaborative effort" on MannKind's bioequivalence studies. (*Id.* ¶ 102.)

Defendants fault Plaintiffs for "never specif[ying] exactly what any of these documents actually says, how those contents contradict the public statements, or when any defendant became aware of those contents," in violation of Ninth Circuit law's admonition that a securities fraud complaint include "adequate corroborating details" and "sufficient detail and foundation necessary to meet either the particularity or strong inference requirements of the PSLRA." (Mem. at 13) (citing *Silicon Graphics*, 183 F.3d at 985; *Tellabs*, 551 U.S. at 326).

As discussed above, Defendants have not made available the FDA's 2011 CRL. Accordingly, Plaintiffs have relied partly on inference in order to demonstrate that Defendants' statements were known to be false when made. Until recently, the Ninth Circuit adhered to a general rule finding inadequate "complaints alleging that 'facts critical to a business's core operations or an important transaction generally are so apparent that their knowledge may be attributed to the company and its key officers.' " *Zucco*, 552 F.3d at 1000. In *South Ferry*, however, the court

acknowledged exceptions to that general rule:

> In summary, allegations regarding management's role in a company may be relevant and help to satisfy the PSLRA scienter requirement in three circumstances. First, the allegations may be used in any form along with other allegations that, when read together, raise an inference of scienter that is "cogent and compelling, thus strong in light of other explanations." *Tellabs.* This view takes such allegations into account when evaluating all circumstances together. Second, such allegations may independently satisfy the PSLRA where they are particular and suggest that defendants had actual access to the disputed information, as in *Daou* and *Oracle.* Finally, such allegations may conceivably satisfy the PSLRA standard in a more bare form, without accompanying particularized allegations, in rare circumstances where the nature of the relevant fact is of such prominence that it would be "absurd" to suggest that management was without knowledge of the matter.
>
> ***16** 542 F.3d at 785–786.

Accordingly, Plaintiffs' allegations support a finding of scienter under *South Ferry's* first and third enumerated exceptions. Along with Plaintiffs' other allegations, Defendants' positions within MannKind raise an inference of scienter based on the falsity of the statements and Defendants' access to information contradicting those statements. Moreover, the company's interactions with the FDA regarding AFREZZA approval were absolutely integral to the company's success, and it would therefore "be 'absurd' to suggest that management was without knowledge of the matter."

iv. Conclusion re: Scienter

In light of the foregoing, and pursuant to the *Tellabs* inquiry, the Court finds that Plaintiffs have made a sufficient showing of scienter with respect to Defendants' statements concerning FDA approval of or agreement with the approach being used in their bioequivalency studies.

b. Loss Causation

Defendants also contend that Plaintiffs have failed to adequately plead "loss causation," as "the stock drop was caused by an independent, intervening discretionary judgment by a government agency that had balanced the benefits and risks of an NDA and decided not to approve it without further supporting information." (Mem. at 24.) "Therefore," Defendants argue, "any loss associated with this disclosure was due to the FDA's adverse decision, and not the correction of any false statement or revelation of any fraud." (*Id.*)

As Plaintiffs argue, "[t]his is a distinction without a difference." (Opp. at 23.) Loss causation is defined as "a causal connection between the material misrepresentation and the loss." *Dura Pharmaceuticals*, 544 U.S. at 341. As Plaintiffs argue, "the FDA's rejection both revealed the falsity of defendants' prior statements and was a materialization of the previously undisclosed risks—*e.g.*, that MannKind had not in fact received pre-approval of its testing protocol (in writing, as required by law for such agreements) and that its testing had not successfully proved bioequivalence under applicable FDA standards. This caused MannKind's stock to drop 32% on record trading volume." (Opp. at 24.)

The Court agrees with Plaintiffs' characterization of Defendants' loss causation argument. Defendants essentially seek to parlay their contention that Plaintiffs have failed to demonstrate falsity into an argument that Plaintiffs have failed to show loss causation. Defendants reason that if the statements were not false, investors understood the particular risks MannKind faced during the approval process; if investors understood these risks, the statements cannot be said to have been the cause of the subsequent drop in the company's stock price. Defendants may also reason that even if these statements *were* false, because the FDA's rejection of the 2010 NDA submission was unrelated to bioequivalence, it was not a "materialization" of the previously undisclosed risks. Because the Court has already rejected Defendants' arguments as to falsity and scienter, and its reading of the facts surrounding the 2011 response letter, it rejects Defendants' loss causation argument as well, which is merely derivative of these earlier discussed arguments.

c. Whether the Statements are Actionable

***17** Finally, Defendants argue that the alleged misstatements are not actionable under § 10(b). First, Defendants argue that statements of opinion or optimism are not actionable under the relevant case law. Second, Defendants argue that their statements are

protected by PSLRA's safe harbor, which immunizes certain "forward-looking statements" accompanied by meaningful risk warnings. (Mem. at 21–23.)

In support of their first contention, Defendants cite *In re Cutera Sec. Litig.*, in which the Ninth Circuit affirmed the generally accepted proposition that "feel good monikers" or "mildly optimistic, subjective assessment[s] ... hardly amount[ ] to a securities violation." 610 F.3d 1103, 1111 (9th Cir.2010). Defendants cite to examples of Defendants' less egregious statements, such as that their "meeting [with the FDA] was very—seemed to be very supportive (CC ¶ 72–32), or that the company's officers "certainly believe[d] [it had] demonstrated the safety and efficacy of the product." (*Id.* ¶ 85.) Although Defendants are correct on the law, their rendition of the facts is at odds with Plaintiffs' complaint, which, as discussed above, contains far more damaging allegations than Defendants address here.

Defendants argue that the PSLRA's safe harbor applies because "all of the statements that plaintiff challenges were either forward-looking or provided the core factual underpinning for forward-looking opinions." (Mem. at 22.) "The PSLRA defines forward-looking statements as including 'a projection of revenues,' 'plans and objectives of management' and 'assumptions underlying or relating to' the above." *In re Nuvelo, Inc. Securities Litigation*, 668 F.Supp.2d 1217, 1230 (N.D.Cal.2009). 15 U.S.C. § 78u–5(i)(1)(A)(i) provides that one "shall not be liable with respect to any forward-looking statement, whether written or oral, if and to the extent that the forward looking statement is identified as a forward-looking statement, and is accompanied by meaningful cautionary statements identifying important factors that could cause actual results to differ materially from those in the forward-looking statement."

Plaintiffs contend that most, if not all of these statements are not forward-looking in the first instance, and that even if they are construed to be so, the purported risk warnings do not immunize them. (Opp. at 21–21.)

The Court agrees. The problematic statements made by Defendants refer to *past* interactions with the Agency, and do not merely express optimism or confidence about FDA approval. *See In re Portal Software, Inc. Securities Litigation*, 2005 WL 1910923, * 13 (N.D.Cal. Aug.10, 2005) ("the PSLRA's safe harbor provision ... [is not] applicable to statements of historical fact.") (citing *Livid Holdings Ltd. v. Salomon Smith Barney, Inc.*, 403 F.3d 1050, 1056–57 (9th Cir.2005)). *Nuvelo* and *Amylin* are particularly instructive here. In *Nuvelo*, the court found that even optimistic statements regarding a drug's path to regulatory approval were actionable insofar as they "concealed or downplayed known *present* risks related to regulatory approval." 668 F.Supp.2d at 1230; *see also In re Amylin Pharmaceuticals Securities Litigation*, 2003 WL 21500525, at *5 (S.D.Cal. May 1, 2003) ("There is nothing unlawful about taking a calculated risk. However, if, as Plaintiffs allege, Defendants misled Plaintiffs about such risk by making assurances regarding the completeness of the data and the likelihood of FDA approval, Defendants may be held liable.")

***18** Moreover, even if these statements were construed as forward-looking, the warnings given by Defendants were defective. Although Defendants repeatedly cite to these warnings as evidence that investors were fully aware of the risks inherent in the approval process, the warnings themselves were limited to rather boilerplate language concerning the risks inherent in that process, and do not address misstatements concerning their past communications with the FDA. *See Portal*, 2005 WL 1910923, at * 13 ("Mere boilerplate or generic warnings, however, are insufficient; [t]he cautionary warning ought to be precise and relate directly to the forward-looking statements at issue.") (quotation marks omitted); *see also Yanek*, 388 F.Supp.2d at 1123 (cautionary language concerning generic risks of FDA approval process "does not meaningfully address the risks related to [Defendant's] pending FDA approval.")

Accordingly, the Court finds that the statements Plaintiffs have relied upon are actionable under the PSLRA.

3. STATEMENTS CONCERNING ADEQUACY OF BIOEQUIVALENCE STUDIES AND FRAUDULENT ACTIVITY

Although not essential to its ruling, the Court also briefly addresses the second and third categories of statements Plaintiffs allege were false and known to be so when made. *See Tellabs*, 551 U.S. at 323 (The Court must determine "whether all of the facts alleged,

taken collectively, give rise to a strong inference of scienter, not whether any individual allegation, scrutinized in isolation, meets that standard.")

a. Adequacy of Bioequivalence Studies

Plaintiffs cite to a series of statements in which Defendants seek to assure investors that bioequivalence had been "shown" or "established" by MannKind's recent studies. (CC ¶¶ 63, 65, 70, 76, 78, 86.) Plaintiffs allege that such statements were "materially false and/or misleading when made, and made with scienter, because Defendants knew or should have known that" these studies were woefully inadequate to establish bioequivalence in light of significant differences between the first and second generation inhalers, and the way Defendants were conducting them.

The parties argue at some length over whether Defendants could have reasonably believed that the FDA would accept its bioequivalency submissions. For instance, Plaintiffs point to 21 C.F.R. § 320. 1, which defines bioequivalence as "the absence of a significant difference in the rate and extent to which the active ingredient ... in pharmaceutical equivalents ... becomes available at the site of drug action when administered at the same molar dose under similar conditions." Because the "molar dose" differed between MedTone C and Dreamboat, Plaintiffs argue that Defendants could not have believed that the company's bioequivalence studies had any chance of securing FDA approval, as they did not comply with FDA regulations. Defendants, on the other hand, argue that under *Bristol–Myers Squibb Co. v. Shalala*, the FDA enjoys "wide discretion to determine how the bioequivalency requirement is met," and thus Defendants acted in reliance on that discretion. 923 F.Supp. 212, 218 (D.D.C.1996). (Mem. at 11.) Plaintiffs reply that the *Bristol–Myers Squibb Co.* rule applies only to the approval of generic drugs. (Opp. at 7–8, n. 6.) Defendants also argue that pursuant to FDA guidance, the company could have plausibly relied on clinical safety and efficacy data obtained with the MedTone inhaler, and that they could have plausibly believed that bioequivalence studies using healthy subjects would satisfy FDA standards, contrary to Plaintiffs' repeated assertions that MannKind "had no safety data that could support its resubmitted NDA for Dreamboat" and must have known as much. (Mem. at 11–12.)

***19** The Court finds that these allegations, taken alone, do not reach the level of "deliberate recklessness" required by the case law. Rather, they merely point to what Plaintiffs allege are the somewhat amateurish—as opposed to fraudulent—aspects of Defendants' business venture. The parties argue at length over whether FDA guidance and Pfizer's experience with Exubera provided MannKind with support for their belief that the bioequivalency studies being conducted were adequate. That they can argue about these matters at such length does not help Plaintiffs' contention here, which is premised on the theory that such decisions and statements were so far outside the realm of reasonableness as to be false and made with "deliberate recklessness" as to their veracity. Moreover, if these statements *were* made with knowledge of their falsity, Plaintiffs have not offered any reason as to why Defendants would move forward with data that they knew would be unlikely to satisfy the FDA. In contrast, it is easily understood why Defendants would misstate details concerning their collaboration with the Agency, so as to instill in investors the impression that approval was a more certain prospect than it in fact was.

As noted above, however, these statements serve to buttress, even if they are not necessary to Plaintiffs' reading of the 2011 CRL. Accordingly, as part of a holistic *Tellabs* inquiry, they do support a finding of scienter.

b. Statements Concerning Fraudulent Activity

Plaintiffs also point to a lawsuit filed by John Arditi, MannKind's former Senior Worldwide Director of Regulatory Affairs, alleging "potential fraud and scientific misconduct in at least two Eastern European clinical sites tainting data that MannKind submitted to the FDA as part of its NDA." (CC ¶ 90.) Arditi alleged that he had warned MannKind's Vice President of Regulatory Affairs of these problems a year earlier, and that he had confirmed audit concerns regarding widespread potential fraud and scientific misconduct in connection with the AFREZZA studies. (*Id.* ¶¶ 91–95.) Plaintiffs allege that "[f]or over a year, MannKind concealed from investors that there were problems with the ... clinical sites and, as a result, problems with the data submitted to the FDA." (*Id.* ¶ 96.) Moreover, Plaintiffs allege that "[w]hen MannKind finally did disclose the Arditi lawsuit, its November 4, 2010 press release was materially false and/or misleading because it omitted that the FDA

would have to investigate the accusations raised therein, likely delaying approval even if MannKind had provided sufficient evidence in support of its 2010 NDA resubmission." (*Id.* ¶ 97.)

Defendants contend that "plaintiff never identifies, as he must, what in the complained-of press release was misleading ... [and] likely fails to explain how or why the alleged problems in or investigation of foreign clinical trial sites negatively affected AFREZZA's prospects for approval." (Mem. at 20.)

***20** It is true that Plaintiffs have not pleaded this allegation with the specificity with which they have pleaded their other allegations. Nevertheless, as a further consideration in a holistic *Tellabs* inquiry, these omissions do support Plaintiffs' claim that MannKind had a pattern of being less than forthright with its investors concerning potential hiccups in the FDA approval process. As the Court noted above, the case law provides support for the use of statements such as these to establish scienter.

4. CONCLUSION RE: § 10(B) CLAIM

For the reasons set forth above, the Court finds that the alleged misstatements, taken together, are sufficient to show a "strong inference" of scienter; that Plaintiffs have adequately pleaded loss causation; and that the statements Plaintiffs rely upon are actionable under the PSLRA. Accordingly, Defendants' motion to dismiss Plaintiffs' cause of action for violations of § 10(b) of the Securities Exchange Act is **DENIED.**

5. SECTION 20(A) CLAIM

Defendants also move to dismiss Plaintiffs' cause of action under § 20(a) of the Exchange Act, arguing that it must fail with their § 10(b) claim. Defendants further argue that "even if plaintiff had alleged a primary violation, dismissal would be appropriate as plaintiff has not pled with specificity facts showing each defendant's ability to exercise control over the activity on which the primary violation is premised." (Mem. at 24.)

§ 20(a) of the Exchange Act provides that:

> Every person who, directly or indirectly, controls any person liable under any provision of this chapter or of any rule or regulation thereunder shall also be liable jointly and severally with and to the same extent as such controlled person to any person to whom such controlled person is liable, unless the controlling person acted in good faith and did not directly or indirectly induce the act or acts constituting the violation or cause of action.

15 U.S.C. § 78t(a). The Ninth Circuit has held that "in order to prove a prima facie case under § 20(a), plaintiff must prove: (1) a primary violation of federal securities laws ... and (2) that the defendant exercised actual power or control over the primary violator." *Howard v. Everex Sys.*, Inc., 228 F.3d 1057, 1065 (9th Cir.2000). Whether a defendant "is a controlling person is an intensely factual question, involving scrutiny of the defendant's participation in the day-to-day affairs of the corporation and the defendant's power to control corporate actions." *Kaplan v. Rose*, 49 F.3d 1363, 1382 (9th Cir.1994) (internal quotation marks and citations omitted). "In order to make out a prima facie case, it is not necessary to show actual participation or the exercise of actual power; however, a defendant is entitled to a good faith defense if he can show no scienter and an effective lack of participation." *Howard*, 228 F.3d at 1065. The defendant bears the burden of proving he "acted in good faith and did not directly or indirectly induce the violations." *Id.*

***21** Plaintiffs have adequately pleaded a § 20(a) cause of action. Plaintiffs have pleaded a primary violation of federal securities laws under § 10(b), and have alleged that Defendants are "controlling" persons within the meaning of the Exchange Act. (CC ¶¶ 30–33, 102, 124–125, 130.) Defendants have made no showing of good faith to rebut that prima facie case.

Accordingly, Defendants' motion to dismiss Plaintiffs' cause of action under § 20(a) is **DENIED.**

B. MOTION TO STRIKE

In their separate motion to strike, Defendants contend that the expert report attached to Plaintiffs' complaint, as well as the portions of Plaintiffs' complaint that rely on that expert's opinions should be stricken under Fed.R.Civ.P. 12(f). Defendants argue that the report is not a "written instrument" under Fed.R.Civ.P. 10(c), and therefore cannot properly be considered as part of the Plaintiffs' complaint on a 12(b)(6) motion. (Docket No. 58, Mem. ("MTS–Mem.") at 1.) Defendants further characterize the report as offering "nothing more than Dr. Guarino's unsupported, hindsight-based opinions,"

which are "immaterial and impertinent to the questions before the Court" on Defendants' motion to dismiss. (*Id.* at 1.)

1. LEGAL STANDARDS UNDER FEDERAL RULES OF CIVIL PROCEDURE 12(F) AND 10(C)

Under Fed.R.Civ.P. 12(f), "[t]he court may strike from a pleading an insufficient defense or any redundant, immaterial, impertinent, or scandalous matter." Under Fed.R.Civ.P. 10(c), "[a] copy of a written instrument that is an exhibit to a pleading is a part of the pleading for all purposes." Several courts addressing the issue have found that Fed.R.Civ.P. 10(c) "only permits the incorporation of a legally operable 'written instrument' such as a contract, check, letter, or affidavit," but not "items such as 'newspaper articles, commentaries and editorial cartoons.' " *Dichter–Mad Family Partners, LLP v. U.S.*, 707 F.Supp.2d 1016, 1019 (C.D.Cal.2010) (citing *Rennie & Laughlin, Inc. v. Chrysler Corp.*, 242 F.2d 208, 209 (9th Cir.1957)); Wright & Miller, 5A *Federal Practice & Procedure* § 1327 n. 1 (3d ed.2009 update); *Perkins v. Silverstein*, 939 F.2d 463, 467 n. 2 (7th Cir.1991); *see also Montgomery v. Buege*, 2009 WL 1034518, *3 (E.D.Cal. Apr.16, 2009) ("The types of instruments that qualify for incorporation under Rule 10(c) consist largely of documentary evidence, specifically, contracts, notes, and other writings on which a party's action or defense is based.") (citing *DeMarco v. DepoTech Corp.*, 149 F.Supp.2d 1212, 1220 (S.D.Cal.2001)). However, the Ninth Circuit has held that "affidavits and declarations ... are not allowed as pleading exhibits ***unless they form the basis of the complaint."*** *United States v. Ritchie*, 342 F.3d 903, 908 (9th Cir.2003) (emphasis added).

2. APPLICATION TO DEFENDANTS' MOTION TO STRIKE PLAINTIFFS' EXPERT REPORT

Both parties cite to *DeMarco*, in which the court reasoned as follows:

> ***22** The Court further questions whether any good reason exists for a plaintiff to attach an expert affidavit as an exhibit to a complaint. The inclusion of such an affidavit in no way relieves a plaintiff of its burden to comply with the Reform Act and the applicable provisions of the Federal Rules of Civil Procedure. Because the Court must generally assume the truth of all material factual allegations in a complaint, averments in an expert affidavit carry no additional probative weight merely because they appear within an affidavit rather than numbered paragraphs of the complaint. A securities fraud complaint must, regardless of its form and attachments, provide the factual specificity required by the Reform Act and Rule 9(b). Conclusory allegations and speculation carry no additional weight merely because a plaintiff placed them within the affidavit of a retained expert.
>
> A better approach might be to include the expert's nonconclusory assertions within specific paragraphs in the complaint. This would reduce needless redundancy and simplify pleadings in federal securities cases. Indeed, Plaintiffs replicated almost all of the relevant portions of Dr. Makuch's affidavit in several paragraphs of the Second Amended Complaint.

149 F.Supp.2d at 1221–1222. The court therefore held that the affidavit did not qualify as a "written instrument" under Rule 10(c), and granted the motion to strike. *Id.* It did not, however, strike the portions of the plaintiff's complaint that relied on the expert's report. Defendants also cite to *Stuart v. Cadbury Adams USA, LLC*, in which the court found that an attached expert report is not a written instrument under Rule 10(c). 2010 WL 1407303, *4 (C.D.Cal. Apr.5, 2010).

Plaintiffs cite to cases, notably *DLJ Mortg. Cap. Inc. v. Kontogiannis*, 726 F.Supp.2d 225, 234 (E.D.N.Y.2010), in which courts have considered expert affidavits and reports, and argues that "as there is no hard and fast rule regarding the status of expert affidavits with pleadings," the Court should "support consideration of Dr. Guarino's full report." (Docket No. 65, Opp. ("MTS–Opp.") at 4.)

As an initial matter, the Court reiterates that the expert report is not essential to its finding that Plaintiffs' complaint survives Defendants' motion to dismiss. The report is used primarily to (1) demonstrate that it would be a deviation from standard FDA practice to reach an unenforceable agreement with MannKind as to bioequvialency protocol, or to pre-approve a protocol that the Agency would later reject; and (2) that the bioequivalency studies were woefully inadequate. The first set of assertions help to establish that Defendants were misrepresenting the facts when they told investors that their studies were

"pre-approved," "blessed," and so on. As discussed above, however, Plaintiffs have other evidence demonstrating falsity for these statements. As to the second set of opinions, the Court has already concluded that the statements concerning the actual merits of the bioequivalency studies are not critical to the complaint's pleading of scienter, and insofar as they are relevant, the expert report is not determinative as to the strength of those allegations.

***23** The Court agrees with the findings in *DLJ Mortg. Cap.*, namely that there exists "no inflexible rule" governing the sort of "written instruments" that may be attached to a pleading. 726 F.Supp.2d at 234. The expert report serves merely to buttress Plaintiffs' contentions concerning the lack of an agreement or understanding with the FDA and the inadequacy of Defendants' bioequivalency studies, upon which Plaintiffs' complaint rests. The Court will therefore allow the expert report to stand, and the motion to strike is **DENIED.**

IV. CONCLUSION

For the reasons set forth above, the Court **DENIES** Defendants' motions to dismiss Plaintiffs' complaint and to strike the expert report attached thereto.

C.D.Cal.,2011.
In re MannKind Securities Actions
Not Reported in F.Supp.2d, 2011 WL 6327089 (C.D.Cal.)

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